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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,293	02/25/2002	Mark W. Leiby	68703/152	7984

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,293

Applicant(s)

LEIBY ET AL.

Examiner

Jennifer K. Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-23 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 10, 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 9 and 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4, 8-9, and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The addition of the limitation requiring the nozzle to be positioned a distance of greater than 5cm from the substrate appears to be new matter. Examiner is unable to find, in the originally-filed disclosure, a teaching of said distance. Regarding Applicant's arguments that said limitation is inherent in Figure 1, Examiner disagrees. Proportions of features in a drawing are not evidence of actual proportions when drawings are not to scale. It is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue. When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. MPEP 2125. Examiner is unable to find any reference to the size or scale of the

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coating apparatus of Applicant. The drawing does not provide basis for a nozzle distance to the substrate.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 11-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (6,153,252).

Hossainy et al. teach a process for coating a stent substrate with an organic compound in a containment system by spraying an organic (polymeric) compound in solvent (liquid) via an ultrasonic nozzle to form micron-sized droplets, which impact on the substrate. Hossainy teaches subsequent drying, which removes the solvent (Example 6). Hossainy's containment system is used to slow evaporation and functions as Applicant's chamber. The pressure used by Hossainy is inherently controlled. Since the containment system is used to slow evaporation, the liquid is inherently volatile because evaporation occurs. Since the same type of SonoTek ultrasonic nozzle, droplet size, volatile liquid (col. 6, line 66), "cloud" coating formation, and substrate is used by Hossainy as by Applicant, the microdroplets formed by Hossainy must inherently impact "isotropically" on the surface of Hossainy's stent in the same manner of impact as Applicant's method. Hossainy teaches coating stents, which are 3-D, with a film-forming layer, qualifying as "conformal".

Regarding the newly-added limitation requiring the distance of the nozzle to be "greater than 5 cm from the substrate", Examiner notes that Hossainy teaches said distance to be 1.5-5 cm. It is Examiner's position that Applicant's range is not patentable over the teaching of Hossainy. A *prima facie* case of obviousness exists where the claimed range and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties (MPEP 2144.05; *Titanium*

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Metals Corp. of America v. Banner, 778 F. 2d 775, 227 USPQ! 773 (Fed. Cir. 1985)).

Applicant's requirement for "greater than 5cm" is "close enough" to 5 cm that one skilled in the art would have expected the same properties. The phrase "greater than 5 cm" is open to a measurement larger than 5cm by only an imperceptible amount such that the same results would be obtained by Applicant as Hossainy using a distance of 5 cm.

7. Claims 1-4, 8, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. in view of Versteeg et al.

Hossainy et al. teach that which is disclosed above regarding coating a medical device in a chamber with an organic compound solution in a cloud formation with a Sono-Tek ultrasonic coater and then drying the coating. Hossainy et al. teaches that control of solvent evaporation is achieved by using a containment device, but fails to teach the mechanism and specifics of the use of such evaporation-control device.

Versteeg teaches that which is disclosed above regarding coating a substrate in a cloud of organic material formed in a pressure-controlled chamber and applied with a Sono-Tek ultrasonic coater using a metering, evacuating, and purging step as outlined above.

Since Hossainy and Versteeg both coat substrates with organic materials using the same ultrasonic coaters in a chamber and Versteeg specifically teaches the use of metering, evacuating, purging, and pressure-controlling to control evaporation of the solvent as also desired by Hossainy, Versteeg would have reasonably suggested the use of metering, evacuating, and purging, in the method of Hossainy. It would have been obvious to one of ordinary skill in the art to use the metering, evacuating, etc.

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conditions of Versteeg in the method of Hossainy to provide reproducible, uniform coatings in the method of Hossainy.

Hossainy teaches coating stents, which are 3-D, with a film-forming layer, qualifying as "conformal".

Regarding the newly-added limitation requiring the distance of the nozzle to be "greater than 5 cm from the substrate", Examiner notes that Hossainy teaches said distance to be 1.5-5 cm. It is Examiner's position that Applicant's range is not patentable over the teaching of Hossainy for the reasons outlined above.

Hossainy's stent includes drug layers which inhibit restenosis.

It would have been obvious to use Versteeg's inert gases to dry the coating of Hossainy.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy in view of Versteeg as applied to claims 1, 3-4, and 8 above, and further in view of Tedechi.

Hossainy in view of Versteeg teach that which is disclosed above including a method of coating stents with polymer coatings with drugs incorporated therein, but fails to specifically teach that the polymer coating may be a derivatized silane.

Tedechi teaches coating stents with derivatized silane polymer with drugs incorporated therein to provide a thromboresistant, biocompatible coating.

Since Hossainy in view of Versteeg teach coating stents with polymers and Tedechi teaches a suitable polymer for coating stents, Tedechi would have reasonably suggested the use of derivatized silane as the polymer in Hossainy in view of Tedechi. It would have been obvious to one of ordinary skill in the art to use the teachings of Tedechi in the method of Hossainy in view of Versteeg to provide a biocompatible, thromboresistant coating in the method of Hossainy in view of Versteeg.

Response to Arguments

9. Applicant's arguments filed 2/10/2005 have been fully considered but they are not persuasive. Examiner has addressed each of Applicant's arguments in the body of the rejections, above.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Tuesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JENNIFER MICHENER
PRIMARY EXAMINER

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April 17, 2005